March 7, 2023

By ECF

Honorable Edward S. Kiel, U.S.M.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Federal Square, Courtroom 8
Newark, New Jersey 07101

Re: ***United States ex rel. Silbersher v. Janssen Biotech Inc., et al.*,**
Civil Action No. 19-12107 (KM-ESK)

Dear Judge Kiel:

We submit this joint letter on behalf of the parties in the above-captioned matter pursuant to Civil Local Rule 37.1 governing discovery disputes and the Court's Case Management Order.

On August 17 and December 9, 2022, the parties met and conferred in good faith in an attempt to resolve several disputes related to Relator Zachary Silbersher's responses to Defendants' Amended Requests for Production ("RFPs"). The parties also exchanged letters and emails concerning these issues on August 5, September 7, October 10, November 17, and December 16, 2022. Defendants respectfully request that the Court resolve the disputes detailed below regarding Defendants' efforts to obtain discovery.

I. Background

Defendants' Statement of the Relevant Background

Relator's lawsuit concerns Defendants' procurement of U.S. Patent No. 8,822,438 (the "'438 Patent"), which covered sales of the prostate cancer drug Zytiga. The '438 Patent was the subject of prior patent infringement litigation ("the underlying patent litigation") and *inter partes* review ("IPR") proceedings between the Janssen Defendants and several generic-drug manufacturers. At its core, Relator's lawsuit contends that Defendants fraudulently procured the '438 Patent by knowingly submitting papers to the United States Patent Office ("USPTO") that allegedly contain purported omissions, misrepresentations, and misleading information regarding Zytiga's commercial success. Relator alleges that Defendants then submitted false claims overcharging governmental entities for Zytiga based upon the '438 Patent.

Relator is a patent attorney with Kroub, Silbersher & Kolmykov PLLC, "whose practice focuses on investigating invalid pharmaceutical patents that brand manufacturers use to protect their drugs from price competition." Compl. ¶ 16, ECF 63. In addition to his legal practice, Relator provides patent-related analysis on a non-attorney-client basis. *See* Compl. ¶ 16. Specifically, Relator owns and operates Markman Advisors, a consulting firm that is separate and independent from Relator's law firm. In his consulting capacity, Relator advises clients on patent valuation,

investment consulting relating to pending patent litigation (with an emphasis on pharmaceuticals and the Hatch-Waxman Act), patent monetization, and litigation funding.[1] Further, Relator frequently serves as an industry pundit, offering his insight on patent-related issues and cases both as a source for media reporters[2] as well as an author of his own patent blog.[3]

Relator claims that "[t]hrough his independent investigation, [he] has uncovered information supporting the claims set forth" in his Complaint and that his "independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed [sic] allegations and transactions." Compl. ¶ 16. In previous briefing materials, Relator has attributed the allegations in the Complaint to his "substantial technical expertise." Opposition to Defs. Motion to Dismiss at 22, ECF 146. Relator therefore places substantial weight on his experience as both a patent attorney and consultant in order to bring this case. And lastly, Relator has identified himself as an individual likely to have relevant information. *See* Relator's Initial Disclosures at 3 (Exhibit A).

Defendants served an amended initial set of 33 RFPs on March 25, 2022 (Exhibit B); three additional RFPs on October 27, 2022; 14 interrogatories on October 27, 2022; and five interrogatories on February 8, 2023. To date, Relator has produced only 100 documents in response to Defendants' requests. This joint letter concerns a dispute over the extent of Relator's efforts in response to Defendants' RFPs, including certain positions Relator has taken as to privilege and relevance in response to those RFPs. Defendants must, as an initial matter, understand what exists in response to these requests. Relator's refusal, however, to search for responsive material in his consultancy files or after the date he first contacted counsel impedes Defendants' ability to undertake even that threshold assessment and further prevents Defendants from challenging the bases for withholding, including any assertions of privilege.

Relator's Statement of Relevant Background

This case concerns material omissions and misleading statements that Janssen and Johnson & Johnson made to the Patent Office to obtain a patent that they used to exclude generic competitors. As Defendants have repeatedly told the Court, Relator is an outsider to the relevant transactions—he neither worked for any Defendants, nor any generic competitor. The proper scope of discovery focuses on Defendants, not Relator, who is not a percipient witness to any relevant transaction at issue.

Nevertheless, Relator has provided Defendants with all documents in his possession concerning his investigation of the patents and drug at issue in this litigation prior to contacting counsel—his subsequent research and investigation after contacting counsel were all conducted at the direct of counsel. Relator has confirmed that neither he, nor a third-party consulting firm, Markman Advisors, has ever been retained by any client for a consulting assignment involving

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[1] *See* Services, *Markman Advisors*, https://www.markmanadvisors.com/

[2] *See, e.g.*, Valerie Bauman, Bloomberg Law, *Government May Have Ownership or Rights to Coronavirus Vaccines* (March 20, 2020), https://news.bloomberglaw.com/pharma-and-life-sciences/government-may-have-ownership-or-rights-to-coronavirus-vaccines

[3] Zachary Silbersher, *Markman Advisors Patent Blog*, https://www.markmanadvisors.com/blog

any patent, drug, or transaction at issue in this case.

The current discovery disputes arose because Defendants seek documents concerning Relator's and Markman Advisors' confidential advice to clients, on the spurious theory that Relator's views on patent issues *in general* with respect to completely different patents and drugs are somehow relevant to this case. They are wrong. Relator asserts claims on behalf of the Government—his advice to his clients on general patent issues rendered for completely different matters having nothing to do with any of the patents at issue in this case are irrelevant. Relator's allegations on behalf of the Government will be assessed against existing patent law standards, not against Relator's personal views of those standards. Accordingly, Defendants' claim that Relator's advice to his clients on patent issues in general may damage his credibility is neither a defense to the allegations in this case, nor relevant to those allegations. At best, some of Defendants' requested discovery on some general patent issues perhaps may be appropriate during expert discovery for designated testifying experts on patent matters, but not for Relator during fact discovery.

Defendants also improperly sought to discover the identity of Markman Advisors' confidential client list, none of whom retained the consulting firm or Relator for any matter relating to this case. Defendants have asserted that they need Markman Advisors' client lists to conduct their own investigation, and Relator has objected that if Defendants either subpoena or contact Markman Advisors' clients, that would be both harassing and potentially detrimental to his business. Defendants claim they do not intend to subpoena any of Markman Advisors' clients, but have not otherwise identified what type of investigation they intend to conduct into Markman Advisors' clients. Yet, as set forth below, this dispute now appears to be moot because Defendants have indicated they are no longer seeking Markman Advisors' client list. Rather, they now only seek certain documents provided to Markman Advisors' clients with client names redacted. Even this position should be rejected, because Markman Advisors' advice to its clients on completely unrelated matters is not a proper subject of discovery in this case.

II. Specific Issues

A. Request 26[4]

Defendants' Position: Relator's Objections to Producing Consulting Material Related to Topics Implicated by this Case are Without Merit.

As described above, Relator and/or Markman Advisors—in which Relator has an ownership interest—offer consulting services and/or advice on patent valuation and monetization, investment strategies, and litigation funding, each of which involve "assessing the strengths and

[4] RFP 26 seeks: "All documents provided to any of Your or Markman Advisors' consulting clients or potential consulting clients relating to (a) fraud or inequitable conduct in a patent prosecution; (b) the effect and/or propriety of obtaining multiple patents on a single brand name drug; (c) the use or application of a 'commercial success' argument to procure a patent; and/or (d) theories of liability for conduct before the USPTO." Ex. B at 8.

weaknesses of patents."[5] In opining on the strength or weakness of any given patent, Relator is expressing views on the merits of the grounds for issuing the patent, including whether the basis for patentability was reasonably asserted.

Defendants have therefore requested specific, discrete sets of documents from Relator's patent consultant work that would provide insight into the veracity of certain allegations made by Relator in his Complaint relating to industry standards of care. Specifically, Defendants seek documents provided to Relator's and Markman Advisors' consulting clients pertaining to (1) patent prosecution fraud and inequitable conduct; (2) the effects of multiple patents on brand name drugs; (3) the use and application of a commercial success argument in a patent prosecution; and (4) theories of liability for conduct before the USTPO. *See* Ex. B at 8. Defendants expect that this would include memoranda or communications:

- Evaluating merits of pending or potential patent litigation, particularly those involving allegations of inequitable conduct before the PTO or the assertion of a commercial success argument by the patentee;

- Assessing the relative strengths and weakness of a particular patent, as well as any impact of that patent on the drug's price; or

- Discussing the standards or bases for liability based on conduct before the USPTO.

Relator's lone objection to this request is relevance, on the grounds that the requested material does not concern Defendants or Zytiga. Relator's Resp. and Obj. to Defs. RFPs, at 14–15 (Exhibit C); Oct. 10, 2022 Letter from N. Herrera at 3 (Exhibit D). Relator further claims that his consulting client list is confidential and proprietary (although not privileged) and, on that basis, has refused to even search his consulting files for potentially responsive material. Relator's relevance objections are without merit and improperly deprive Defendants of the opportunity to identify and gather information that is both relevant and probative to their defense. Moreover, his refusal to even search and identify potentially responsive material prevents Defendants from testing Relator's grounds for refusing to produce responsive materials.[6]

Importantly, "[r]elevance is a broader inquiry at the discovery stage than at the trial stage." *NLRB v. 710 Long Ridge Rd. Op. Co.*, 2020 WL 3026523, at *2 (D.N.J. June 5, 2020). Thus, "[t]he party resisting production of discovery ordinarily bears the burden of establishing lack of relevancy." *Baier v. Princeton Office Park, L.P.*, 2018 WL 5253288, at *4 (D.N.J. Oct. 22, 2018)

[5] *E.g.*, https://www.markmanadvisors.com/valuation

[6] Further, Relator's insistence that he "has not otherwise shielded his views on patent law, pharmaceuticals and drug pricing" is incorrect. *Infra* at 6. Defendants requested that Relator produce "[a]ll documents relating to . . . "any articles, posts, or commentary" Relator authored on certain patent law topics. RFP 13, Ex. B at 7–8. Although Relator has produced documents (in the form of screenshots of his LinkedIn and the Markman Advisors blog) listing these articles, he has refused to produce, or even search for other documents, including drafts, emails, research, and notes relating to articles encompassed by Defendants' request. Defendants, however, are not presently asking this Court to resolve this narrow dispute.

(quotation omitted). The objecting party also bears the burden of showing that the request does not satisfy "the broad scope of relevance defined pursuant to Federal Rule of Civil Procedure 26(b)(1) or else [is] of such marginal relevance that the potential harm occasioned by discovery would outweigh the ordinary presumption in favor of broad disclosure." *Id.* Relator does neither here.

Relator's views on the sought-after topics are relevant because he has called into question the reasonableness of Defendants' actions, including compliance with industry standards, in pursuing, prosecuting, and defending the '438 Patent, and he has relied on his patent education, training, experience, or the like to identify and uncover the alleged misconduct. For instance, Relator has accused Johnson & Johnson attorneys of engaging in unreasonable tactics before the USPTO while asserting Zytiga's commercial success as a secondary consideration in support of the '438 Patent that not only rendered the patent invalid but amounted to fraud on the Government. *See, e.g.*, Compl. ¶ 65 ("Defendants' submissions to the Patent Office were false, misleading, and misrepresentative of Zytiga's actual commercial success."), ¶ 84 ("Defendants' representations to the Patent Office concerning Zytiga's share of the mCRPC market was misleading and fraudulent."), ¶ 84(e) ("Defendants' use of patient share data . . . was fraudulent and misleading.").

The only support for these allegations, however, appears to be Relator's personal assessment of what constitutes reasonable or unreasonable prosecution methods. Indeed, Relator's own position set forth below claims that his "expertise" is the value he has provided the Government. *Infra* at 14 ("Relator's *knowledge* is his *expertise*" (emphasis in original)). Relator has relied on his expertise to prepare the Complaint, making such expertise a fair source of discovery. Relator's own assessment of the strengths and weaknesses of patent litigation involving secondary patent applications, the use of commercial success as an indicator of non-obviousness, and standards of conduct before the USPTO are all therefore relevant to, and provide evidence of, what Relator considers to be reasonable and/or appropriate in the course of his own business. Not only is this evidence relevant insofar as it forms the basis for Relator's allegations, but such evidence may also serve to undermine or cast doubt on Relator's own allegations of impropriety or misconduct here. Those views are particularly important because, here, Relator's conduct suggests a lack of belief in his own allegations. The USPTO's Rules of Professional Conduct—which mimic the ABA's Model Rules—require that "[a] practitioner who knows that another practitioner has committed a violation of the USPTO Rules . . . that raises a substantial question as to that practitioner's honesty, trustworthiness or fitness as a practitioner in other respects, shall inform the [Office of Enforcement and Discipline] Director and any other appropriate professional authority." 37 C.F.R. § 11.803(a). Yet Relator has made no such report despite his allegations that Johnson & Johnson attorneys admitted to practice before the USPTO *intentionally* submitted false and misleading information *to* the USPTO. *See* Relator's Resp. to Defs. Interrogatories at 8 (Exhibit E) ("[Relator] states that he has not reported [any attorney] employed by or acting on behalf of J&J to the Patent Office for committing a fraud on, and/or breaching their duty of candor to, the Patent Office."). Relator's analogy to the defense of unclean hands misses the point—even if a relator's improper conduct were not a defense to liability in a *qui tam* action, that does not protect a relator from discovery into the basis of his or her knowledge for the allegations set forth in a complaint (here, Relator's "expertise") and the citation Relator offers does not suggest as much.

Additionally, Relator's suggestion that the confidential and proprietary nature of his consulting clients and materials serves as a shield from search, identification, and disclosure is incorrect. Parties and non-parties alike are frequently required to disclose confidential and proprietary information in the course of litigation, regardless of their preference not to do so. Defendants have produced such information. Relator, as a party and the initiator of this lawsuit, is not somehow immune from this obligation. Indeed, where Relator touts his industry background and experience as critical in pursuing this lawsuit it is no surprise that such background and experience become a valid source of discoverable information. Confidentiality orders, including the one issued in this matter, *see* Stipulated Am. Discovery Confidentiality Order, ECF 175, give parties assurances that the disclosure of confidential and proprietary information will be limited as much as possible and further ensure that such information is used only for the purposes of the case in question. The Federal Rules of Civil Procedure further specify that additional protection may be taken "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense," none of which Relator has claimed or set out with any degree of specificity. Fed. R. Civ. Pro. 26(c)(1)(A). To the extent Relator claims that the identity of his consulting clients would be harassing or embarrassing, Defendants agree that Relator may implement reasonable redactions to the identities of those clients, to the extent responsive consulting materials contain as much, thereby shielding those specific identities from disclosure while allowing the substantive advice to be produced.

Defendants therefore request the Court order Relator to search for material responsive to Request 26 and to produce any such identified material.

Relator's Position

Relator has confirmed that neither he, nor a third-party intellectual property consulting firm named Markman Advisors, ever had a client that retained Relator or Markman Advisors relating to Zytiga or any patent at issue in this litigation. Neither Relator nor Markman Advisors have ever provided consulting advice with respect to Zytiga or any patent in this litigation in connection with any consulting or other work performed on behalf of their clients, so there are no responsive documents relating in any way to the allegations in the Complaint.

To the extent that Defendants contend that they are entitled to take discovery of consulting services provided by Relator or Markman Advisors that relate in any way to intellectual property or patent issues, including the doctrine of inequitable conduct, or involving the pharmaceutical industry, Relator believes such a request is not reasonably calculated to lead to admissible evidence. Whatever consulting advice Relator or Markman Advisors provided to their clients that do not involve the patents or drugs at issue in this lawsuit are completely irrelevant.

Defendants' request is also improper because Relator is not a majority owner of Markman Advisors, and Markman Advisors is not a party to this litigation. Accordingly, Relator does not have possession custody or control over materials provided to clients on behalf of Markman Advisors.

Despite all that, as Defendants themselves recognize, Relator has not otherwise shielded his views on patent law, pharmaceuticals and drug pricing. On the contrary, Relator has published

scores of blog posts that discuss numerous different pharmaceutical patent litigations. Many of those posts discuss the intersection of patents, pharmaceutical drugs, and their joint relationship on pricing in considerable depth. Many of the Relator's blog posts are devoted to evaluating the merits of pending or potential patent litigations, and most of them relate to pharmaceutical patent litigation. Many of those blog posts include discussion of the relative strengths and weaknesses of a particular patent, and they discuss how those strengths and weaknesses may impact a drug's pricing. Relator has separately published articles on the pharmaceutical patents and drug pricing on third-party websites. All of those blog posts and articles are public, and Relator has produced a list of those articles and blog posts to Defendants.

In footnote 6 of this letter, Defendants complain that Relator has refused to even search for "drafts, emails, research, and notes relating to articles" he has published. That is untrue. Defendants are creating the false impression that Relator has been less than forthcoming with his document production. Defendants previously sought "drafts, emails, research, and notes" relating to two self-published blog posts published by Relator and specifically referenced in Defendants' Request 13. Relator produced all drafts of the identified articles, and confirmed there are no further drafts, emails, research or notes that he is withholding. Defendants then dropped the issue and deleted the corresponding sections from this joint letter. Defendants never raised the issue of drafts and emails of other articles unrelated to Zytiga during any meet-and-confers, and the issue is therefore premature to raise with the Court. Defendants concede as much by stating they "are not presently asking this Court to resolve this narrow dispute." So why bring it up now and waste the Court's time? The point of Relator mentioning that he is not "shielding" his views on patent law is because he has published considerable content related to patents, pharmaceuticals, and drug-pricing, and those publications remain public.

To the extent that Defendants believe that Relator's advice to his clients concerning general "industry standards of care" for conduct before the Patent Office, the "assessment of the strengths and weaknesses" of patent litigation involving secondary patent applications, or the viability of "theories of liability for conduct before the USTPO" for completely different patents and drugs are relevant, then at best, those are issues for expert discovery. Should Relator intend to submit expert opinion on such patent issues, Defendants may take appropriate expert discovery concerning the opinions and qualifications of any proffered experts during expert discovery.

To the extent that Defendants seek documents from Markman Advisors, that consulting firm is not a party to this litigation, and Relator is only a minority, non-controlling stakeholder in that entity. Accordingly, should the Court determine for any reason that Markman Advisors may be required to provide documents in this case, Defendants should raise those arguments in a manner that provides Markman Advisors with proper notice and an opportunity to be heard.

Defendants also previously sought Markman Advisors' confidential client list. Defendants originally claimed the client list was necessary so Defendants could conduct their own investigations. Relator objected that if Defendants were to subpoena or contact Markman Advisors' clients, that would be harassing and potentially damaging to Markman Advisors' business. Defendants clarified that they do not intend to subpoena Markman Advisors' clients, but have not clarified what sort of "investigation" they intend to conduct. Nevertheless, this issue is

now moot. As set forth below, Defendants concede they are no longer seeking Markman Advisors' client list. Rather, they now only seek certain documents provided to Markman Advisors' clients with client names redacted.

Finally, Defendants claim that because Relator did not report certain patent attorneys employed by Defendants to the USPTO, that suggests a "lack of belief in his own allegations." That is plainly wrong. Relator's *qui tam* action makes an allegation of fraud, but not necessarily one of inequitable conduct. During examination of the '438 patent, the Examiner asserted that J&J's commercial success argument was insufficient unless based upon market share data. In response, prosecuting attorneys for J&J submitted an amendment response that enclosed an investor presentation by Janssen. It is not clear on the face of the presentation itself, who was the author or contributors.

For the reasons disclosed in Relator's complaint, Defendants through their agents knew, or clearly should have known, that the information disclosed in the investor presentation either misrepresented or omitted material information in response to the Examiner's request for market share data related to a patent application seeking to claim the coadministration of abiraterone acetate and prednisone. Relator's complaint does not allege that any specific patent attorney, applicant, or responsible person was singularly responsible for the intentional misconduct by Defendants. The fact that Relator did not report Defendants' patent prosecution attorneys under 35 USC 11.803(a), is neither dispositive of Defendant's liability in this case, nor a reflection that Relator lacks "belief in his own allegations." Should discovery confirm that any particular patent attorney working for J&J violated his or her ethical obligations, then Relator would be happy to meet and confer with Defendants to jointly report that person to the relevant authorities, as appropriate.

In summary, Defendants arguments are wrong because this *qui tam* case is about Defendants' misconduct; Relator's advice to his clients unrelated to this case is simply irrelevant.

B. RFP Nos. 12, 14, and 15

Defendants' Position: Relator Must Search For and Identify Responsive Materials After the Date He Contacted Counsel and Produce All Non-Privileged Material

Defendants sought from Relator documents relating to any research, investigation, or analysis on (1) the effect of so-called "evergreening" (i.e., the purported practice by which brand-name manufacturers obtain multiple patents on brand-name drugs to maintain high prices, Compl. ¶ 3) and (2) theories of potential liability that could arise from fraudulent conduct before the USPTO. *See* RFP 14, Ex. B at 6. Defendants also requested documents and communications relating to Relator's investigation into the prosecution, issuance, or enforcement of the '438 Patent; the listing of that '438 Patent in the Orange Book; any claims for payment or reimbursement for Zytiga; and/or any other facts related to the subject matter of his lawsuit. *See* RFP 15, Ex. B at 6–7. Defendants thus expect that Relator would produce factual material that he obtained from third-party sources during the course of his investigation. And, to the extent Relator withholds documents responsive to this request on the basis of privilege, Defendants expect that Relator would describe with particularity the documents being withheld and the basis for withholding each

document.

These types of documents are plainly relevant because they relate directly to the subject matter of the Complaint. Relator's Complaint purports to identify certain facts that he claims rendered a submission by Defendants to the USPTO misleading and fraudulent. Many of Relator's allegations claim a specific factual state of affairs, for example:

- Paragraph 83(a) – alleges submission was "fraudulent and misleading" because competitor drug had not yet been approved for patient submarket and subsequently "overtook Zytiga in market share and number of prescriptions written" over a year after approval.

- Paragraph 83(f) – alleges submission was misleading because increased Zytiga share was compared with declining market share of an older anti-androgen drug that was being used in a submarket "only for specific purposes in conjunction with a treatment that was considered to be more efficacious."

- Paragraph 87(g) – claims Zytiga was commercially successful because it is "an oral medication, whereas [competitor] Jevtana is a one-hour intravenous infusion."

- Paragraph 87(i) – claims "abiraterone is prescribed and sold without prednisone at least 10% of the time" and therefore those sales of Zytiga lacked nexus to the claimed invention.

- Paragraphs 16 and 28 – contend that relator has "direct and independent knowledge" of the allegations in the Complaint and that he "uncovered information supporting th[ose] claims" through his own "independent research and investigation."

Relator presumably therefore has documents and/or information providing the predicate for that "direct and independent" knowledge of the factual state of affairs alleged in the Complaint, including (although certainly not limited to) in paragraphs 82 through 88.

Relator's initial Responses and Objections to RFPs 14[7] and 15[8] stated that Relator would

[7] RFP 14 requests: "All documents regarding or relating to any research, investigation, or analysis addressing or evaluating (a) the effect that obtaining multiple patents on a brand name pharmaceutical product has on that product's price or (b) theories of potential liability that could arise from alleged fraudulent or inequitable conduct in a patent prosecution." Ex. B at 6.

[8] RFP 15 requests: "All documents and communications relating to any investigation, including but not limited to the initiation of any such investigation, that You or anyone on Your behalf conducted regarding Defendants' application for, or prosecution or enforcement of, the '438 Patent; the granting of the '438 Patent or the listing of the '438 Patent in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the 'Orange Book'; any Claims for payment or reimbursement for Zytiga; and/or any other facts related to the subject matter of this Litigation." Ex. B at 6–7.

limit his production to "non-privileged, responsive documents in his possession obtained by or created by Plaintiff *prior to Plaintiff contacting counsel*." Ex. C at 8–9 (emphasis added). Relator did not similarly limit his responses to any of Defendants' other requests nor offer any specific objections related to the assertion of privilege. *See, e.g.*, Ex. C at 7 (RFP 12), 12 (RFP 20). Subsequent correspondence, however, indicates that Relator has in fact taken a similar approach to Defendants' other requests:

- In his October 10 letter, Relator stated, for the first time, that in response to RFP 12 he had "searched for, and produced documents concerning his research into Federal and/or State Government contracting, reimbursement, or payment procedures *that were obtained prior to contacting counsel*." Ex. D at 3.

- In that same October 10 letter, Relator represented that he was not withholding documents in response to RFP 20 "on the basis of law of the case or relevance" but failed again to say anything about withholding on the basis of privilege. *Id.* at 2.

- Relator did not make specific objections on the basis of privilege in his December 5, 2022 responses to interrogatories requesting information relating to Relator's "independent investigation." Ex. E at 3–4.

- In his December 16, 2022 letter, however, Relator asserted both "attorney-client privilege and protection of the work product doctrine" over *all* information relating to his independent investigation that led to the Complaint and further that *all* "of his independent investigation was conducted after contacting counsel." Dec. 16, 2022 Letter from N. Herrera at 3 ¶ 10 (Exhibit F).

- According to Relator, he "first contact[ed] Mr. Herrera … to retain him to pursue these cases in September 2016, and retained him soon thereafter, even if a formal agreement was signed later." *Id.* at 1.

In other words, Relator appears to have claimed the umbrella of privilege to categorically exclude from search and identification all documents obtained or created after September 2016—the date of his first contact with his current counsel—from any type of search or review.[9] Relator's position, therefore, effectively cloaks all material relating to the subject matter of this case obtained or created after September 2016 in privilege regardless of whether that privilege actually attaches. *E.g.*, Ex. F at 2 (admitting the existence of "draft articles about these cases that have not yet been published, which were created after Relator retained counsel, and which have been shared with counsel seeking legal advice" and are "therefore covered by the attorney-client privilege"). The validity of Relator's sweeping assertion of privilege aside, he has not identified any authority that would support him to not take the foundational step to search for and identify relevant and

[9] Notably, Relator, with Mr. Herrera as counsel, has pursued two other similar cases, and Relator's reference to contacting Mr. Herrera in September 2016 in connection with "these cases," Ex. F at 1, is vague as to which cases were in scope at the time of the September 2016 initial retention, and whether the instant case fell within the scope at that time.

responsive material before then assessing whether such material is in fact privileged.

Neither the attorney-client privilege nor the work-product privilege relieves Relator of his obligation to conduct a search for responsive material—even if Relator ultimately withholds that material. For that reason, Relator's reference to substantial need or undue hardship under 26(b)(3)(A)—the standard for *production*, not for search and identification—is irrelevant at this point in time, because Relator has not even looked for responsive material. Not even in this letter can Relator specify with clarity what he has withheld on this basis. At times, Relator asserts he is "merely seek[ing] to protect from disclosure the documents and communications . . . that were *prepared* at the direction of counsel," whereas at others he indicates he is withholding documents both "*prepared* or *obtained* by Relator after contacting counsel." *See infra* at 13 (emphases added). Although minor, this distinction proves critical here because Relator has in fact produced documents relating to his investigation that he could not have obtained prior to retaining counsel, including pleadings from the IPR and district court proceedings.

Relator also offers no legal support for the notion that all factual material relating to the subject matter of a complaint becomes cloaked in privilege once counsel is retained. *See, e.g.*, *In re Riddell Concussion Litig.*, 2016 WL 7108455, at *4 (D.N.J. Dec. 5, 2016) ("[T]he attorney-client privilege applies to communications and not facts."); *Koch Materials Co. v. Shore Slurry Seal, Inc.*, 208 F.R.D. 109, 121–22 (D.N.J. 2002) ("[A]lthough the work product doctrine protects against the disclosure of protected documents or communications, it does not protect the underlying facts."). Nor can he. "[T]he collection of evidence, without any creative or analytical input by an attorney or his agent, does not qualify as work product." *Riddell Sports Inc. v. Brooks*, 158 F.R.D. 555, 559 (S.D.N.Y. 1994). There is, therefore, no such presumption that the material being withheld by Relator is actually privileged, particularly to the extent Relator continues to withhold purely factual material he obtained from third-party sources. *See id.* at *6 ("[A] party claiming [work-product] protection must demonstrate the precise manner in which a document is protected. Blanket assertions do not suffice." (internal citations omitted)). Relator's pro forma assertions of privilege to justify the refusal to even search those materials is unsustainable.

Nonetheless, the False Claims Act provides that courts *must* dismiss any action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in one of three enumerated channels, 31 U.S.C. § 3730 (e)(4), making evidence regarding the source of Relator's allegations critical to Defendants' defense in this matter. And Relator's notion that the "original source" inquiry "is no longer at issue," *infra* at 13–14, is incorrect. Although the Court ruled that certain forms of disclosure identified by Defendants in their motion to dismiss did not qualify under the public disclosure bar, ECF 179 at 12–18, nothing in the Court's opinion foreclosed the issue from further discovery; if new evidence regarding the source of Relator's information were uncovered, Defendants would be permitted to raise the issue in that context. Moreover, Relator has previously advised Defendants that he has not withheld documents on the basis of law of the case. *See* Exhibit D at 2. Relator has thus waived any objection on that basis.

Defendants accordingly request the Court to order Relator to search for and identify documents responsive to Defendants' RFPs 12, 14, and 15 and produce all such non-privileged documents.

Relator's Position

As Relator understands Defendants' arguments, Defendants are seeking two types of documents for which there appears to be a dispute between the parties. The first group of documents involves Relator's investigation of the specific patents and drugs at issue in this case. The second group are general documents—unrelated to the patents or drugs at issue in this case—concerning any other research or investigation undertaken by Relator on intellectual property issues generally, but which do not involve the specific patents at issue in this case.

As to the first group, Relator has produced all responsive documents concerning his investigation into the patent fraud alleged in the complaint that he independently conducted prior to contacting counsel to pursue this *qui tam*. Thus, Defendants in request 15 seek documents concerning Relator's investigation into the patents at issue in this case. In response to this request, Relator has produced all responsive documents prior to contacting counsel in September 2016. After that time, all of Relator's research into Zytiga and the patents that Defendants used to protect their monopoly was conducted under the direction of counsel.

As to the post-September 2016 documents, Relator has identified two discrete categories. First, there are communications and memoranda that Relator generated based on Relator's communications with counsel developing and researching this case for filing. All of these documents are privileged, and Defendants do not dispute that. The second category of documents are patent filings, IPR filings, and other documents that Relator identified in his attorney-directed research, and which Relator has downloaded or printed out for his files. (Research materials that Relator merely viewed online or sent to counsel with a hyperlink are not within his current possession or control.) With respect to this second category of documents, Relator has searched for, and produced, all of them. So there really is no dispute with respect to these documents.

Defendants argue and cite cases that the attorney client privilege and work product doctrine does not protect underlying facts. *In re Riddell Concussion Litig.*, 2016 WL 7108455, at *4 (D.N.J. Dec. 5, 2016); *Koch Materials Co. v. Shore Slurry Seal, Inc.*, 208 F.R.D. 109, 121–22 (D.N.J. 2002). Relator agrees. Indeed, Relator has not sought to shield such facts—to the contrary, he has disclosed all relevant facts concerning Defendants' fraud that he is currently aware of in his complaint. Relator merely seeks to protect from disclosure the documents and communications relating to his investigation that were prepared at direction of counsel.

It is abundantly clear that, "based on the surrounding facts and the nature of the materials," any documents prepared or obtained by Relator after contacting counsel in September 2016, "were in fact prepared or obtained because of pending or anticipated litigation." *In re Riddell Concussion Reduction Litigation*, 2016 WL 7108455, at *6 (*quoting Reich v. Hercules, Inc.*, 857 F. Supp. 367, 372 (D.N.J. 1994). And Defendants have not even attempted to argue "substantial need" or "undue hardship" with regard to these materials. Fed. R. Civ. Proc. 26(b)(3)(A).

As to the second group of documents, Defendants seek general documents—unrelated to the patents or drugs at issue in this case—relating to any other general research or investigation undertaken by Relator concerning the effect of patents on drug prices, and the potential liability that could arise from any such conduct. For this group of documents, Relator has produced all of

his own published articles or blog posts relating to intellectual property issues generally. Relator has only withheld documents relating to consulting advice he may have provided to any of his private clients on general intellectual property issues. This type of discovery falls under expert discovery, and Defendants may take appropriate expert discovery concerning the opinions and qualifications of any proffered experts during that phase of litigation.

Defendants are wrong to believe that Relator's non-public thoughts on intellectual property issues in general (and unrelated to the specific patents and conduct in this case) could reasonably lead to the discovery of admissible evidence. Should Relator call or seek to introduce expert opinion on patent laws, Defendants may take appropriate discovery of such experts' opinions during expert discovery. However, Relator's opinions on general patent matters expressed to his private clients simply are not proper discoverable topics for fact discovery. Indeed, courts have held that even a relator's improper *conduct* is irrelevant to a *qui tam* action, because the claims are alleged on behalf of the government as the injured party. Thus, for example, unclean hands is not a defense to liability in a *qui tam* action. *See e.g., U.S. v. Ctr. for Diag. Imag., Inc*., 2011 U.S. Dist. LEXIS 145165, at 5 (W.D. Wash. Dec. 16, 2011) ("The Court notes that the Ninth Circuit has already concluded that a qui tam defendant may not defend an FCA action by asserting that a qui tam plaintiff has unclean hands."); *U.S. ex. re. Donald Gale v. Omnicare, Inc*., Case No. 10-127, at *19-20 (N.D. Ohio, Jul. 23, 2013). *A fortiori*, Relator's advice to consulting clients that are wholly unrelated to any patents, allegations, or drugs at issue in this case is not reasonably likely to lead to admissible evidence and would be disproportionate to the needs of the case.

Defendants say that they wish to take discovery on Relator's status as an "original source" under 31 U.S.C. § 3730(e)(4)(B), so they should be entitled to obtain documents concerning Relator's investigation. To begin with, the "original source" question is no longer at issue, because the Court has already determined that there has been no public disclosure under the False Claims Act. *See* ECF No. 179, at 12-17. Accordingly, the original source question is no longer at issue in this case. *See* ECF No. 179, at n. 18, n. 15. Even if the original source issue were still relevant—and it is not—Defendants are not entitled to more than what Relator has produced. Relator has produced all documents concerning his independent investigation of the patents and transactions relating to this case prior to contacting counsel. Relator's subsequent investigation at the direction of counsel is privileged, and Defendants make no argument otherwise. Nevertheless, in an attempt to reach compromise and avoid motion practice, Relator also produced documents he obtained from third-party sources post-September 2016. Defendants are simply not entitled to more.

Defendants are also mistaken about the nature of an "original source" inquiry. Under the False Claims Act, an original source is someone who "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B). Relator's *knowledge* is his expertise as an intellectual property lawyer; the specific "information" that Relator provided to the Government is all set forth in the complaint. Relator has produced all documents concerning such information, so there is no real dispute about the relevant "information" that Relator provided to the Government.

Finally, to the extent that Defendants seek documents from Markman Advisors, that consulting firm is not a party to this litigation, and Relator is only a minority, non-controlling

stakeholder in that entity. Accordingly, should the Court determine for any reason that Markman Advisors may be required to provide documents in this case, Defendants should raise those arguments in a manner that provides Markman Advisors with proper notice and an opportunity to be heard.

Respectfully submitted,

SILLS CUMMIS & GROSS P.C.

By: */s/ Jeffrey J. Greenbaum*
JEFFREY J. GREENBAUM
jgreenbaum@sillscummis.com
GREGORY E. REID
greid@sillscummis.com
One Riverfront Plaza
Newark, New Jersey 07102
Phone: (973) 643-7000
Facsimile: (973) 643-6500

SIDLEY AUSTIN LLP
GORDON D. TODD (*pro hac vice*)
gtodd@sidley.com
ROBERT D. KEELING (*pro hac vice*)
rkeeling@sidley.com
KIMBERLY LEAMAN (*pro hac vice*)
kimberly.leaman@sidley.com
1501 K Street, N.W.
Washington, DC 20005

Attorneys for Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson

LITE DEPALMA GREENBERG & AFANADOR, LLC

By: */s/ Bruce D. Greenberg*
BRUCE D. GREENBERG
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

HERRERA KENNEDY LLP
NICOMEDES SY HERRERA (*pro hac vice*)
LAURA E. SEIDL (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com
LSeidl@HerreraKennedy.com

SPARACINO PLLC
TEJINDER SINGH (*pro hac vice*)
1920 L Street, NW, Suite 835
Washington, DC 20036
Telephone: (202) 629-3530
TSingh@sparacinopllc.com

Attorneys for Plaintiff-Relator Zachary Silbersher